REMARKS

The Office Action of March 17, 2005 has been received and reviewed. Claims 18, 20, 23 through 26 and 31 through 36 are currently pending. Claims 1 through 17, 19 and 27 through 30 were previously canceled. Applicant notes that the rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103, and the prior rejection under 35 U.S.C. § 112, first paragraph have all been withdrawn.

Interview Summary

Applicants would like to extend their thanks to Examiner Ewoldt, Ph.D. for granting an interview. The personal interview was conducted on June 21, 2005. Present at the interview were Examiner Ewoldt, Allen Turner, and Johan Renes. All of the pending claims, claims 18, 20, 23 through 26 and 31 through 36, were discussed. No agreement was reached during the discussion concerning amendments that would overcome the 35 USC §112, 1st paragraph rejection. Applicants did amend claims 18 and 20 to specify that the claimed patient of claim 18 and 20 was a rheumatoid arthritis patient, as suggested by Examiner Ewoldt, Ph.D.

Claim Rejections under 35 U.S.C. § 112

Claims 18, 20, 23 through 26, and 31 through 36 stand rejected under 35 USC §112, 1st ¶, as assertedly failing to comply with the written description requirement. The Examiner contends that this is a new matter rejection as the "specification and claims as originally filed do not provide support for the invention as now claimed," specifically noting claim 18 as a "method of treating morning stiffness, loss of grip strength, painful joints, or swollen joints" and claim 20 as a "method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level." Applicant respectfully traverses this rejection.

The Examiner basis his contention on the argument that there is not *in haec verba* support for claim 18 and claim 20 in the specification as originally filed. However, such a basis for rejection has been repeatedly rejected by the Court of Appeals for the Federal Circuit. Accordingly, Applicant respectfully submits that the instant claims are supported by the specification and the original claims. In further support, Applicant is submitting the Declaration

of Alan Howarth, Ph.D. The Declaration of Alan Howarth, Ph.D., is submitted as evidence that the originally filed 'use' claims do support method of treatment claims.

Dr. Howarth holds Bachelor of Science (Biological Sciences), Master of Science (Plant Pathology),and Doctor of Philosophy (Plant Virology) degrees from the University of California-Davis, and a J.D. from Brigham Young University. He has 14 years of experience in biotechnology research and teaching, having held appointments at the University of California-Davis, the University of Illinois, and the University of Arizona, and has published scientific papers in the fields of virology, molecular genetics, enzymology, microbiology, and molecular evolution. Prior to co-founding the firm, Dr. Howarth was a patent attorney and partner in a Salt Lake area intellectual property firm. Dr. Howarth's practice focuses on U.S. and international patenting of inventions in the areas of biotechnology, pharmaceuticals, chemistry, and biomedical products. See Declaration of Alan Howarth, Ph.D, ¶ 3.

It is noted that in order to conform to proper U.S. practice, the claims were revised to be directed to "methods of treatment" rather than "use for the treatment of" claims. Such revision is supported by the specification and the plain meaning of the language to one of ordinary skill in the art. See Declaration of Alan Howarth, ¶ 15. The argument presented below specifically cites references in the originally submitted Paris Cooperation Treaty (PCT) specification, PCT/NL95/00370, to support the amendments. Further, the argument below illustrates that the 'Use' claims of the originally submitted specification fully support method of treatment claims.

The 'use' claims of the originally submitted claims directly correspond to method of treatment claims. In this particular context, as a priority document was first filed in Europe, reference to European law and 'use' claims illustrates that 'use' claims would be understood by one of ordinary skill in the art to include method of treatment claims. See Declaration of Alan Howarth, ¶'s 5-10. Accordingly, Applicants amendments are supported by the specification and do not constitute new matter as will be more fully explained below.

To begin, the Federal Circuit has long cautioned that the written description requirement "is not subsumed by the 'possession' inquiry." ***Enzo Biochem, Inc. v. Gen-Probe Inc.***, 63 USPQ2d 1609 (Fed. Cir. 2002). Identity of description is not necessary. ***See, e.g., Crown Operations Int'l, Ltd. v. Solutia Inc.***, 289 F.3d 1367, 1376, 62 USPQ2d 1917, 1922 (Fed. Cir.

2002) ("[T]he disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue."). Identity of that which is described, however, is necessary: "What is claimed by the patent application must be the same as what is disclosed in the specification ... ." ***Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.***, 535 U.S. 722, 122 S. Ct. 1831, 1840, 62 USPQ2d 1705 (2002); ***accord Lockwood v. American Airlines, Inc.***, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Here, the originally filed specification does provide a written description of methods of treatment to one of ordinary skill in the art.

Further support for Applicant's position can be found with reference to the European Patent Convention (EPC). Article 52 of the EPC defines patentable inventions as those that are susceptible of industrial application, which are new and which involve an inventive step. Martin, Todd, PATENTABILITY OF METHODS OF MEDICAL TREATMENT: A COMPARATIVE STUDY, 82 J. Pat. & Trademark Off. Soc'y 381, 390 (June 2000)(A courtesy copy is enclosed with this response and listed on an IDS). The 1973 Munich Convention decided methods for the treatment of humans could represent independent inventions under Article 52. However, Article 52(4) EPC perpetuates the fiction that methods of medical treatment are incapable of industrial application and explicitly excludes such methods by creating a fiction that methods of treatment are not susceptible of industrial application. See id at 391. The exclusion was created to protect a doctor treating a patient from being sued for infringement on a claim of a patent directed toward the method of treatment. See id. As such, companies and individuals have sought claims in countries subject to the EPC that would provide the coverage and protection of a method of treatment claim. See Declaration of Alan Howarth, ¶'s 5-10.

One mechanism that has developed is a method of claiming through 'use' claims. Use claims developed because Article 52(4) EPC does not apply to products (substances or compositions in particular) for use in any of the above mentioned treatment methods. See id at 389. The claims have developed as a use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application. This is now commonly referred to as the "Swiss-type claim" and allowed by the European Patent Office (EPO) as a second medical use type claim. A first medical use, also allowed by the EPC, is a claim to a

known compound in an appropriate composition suitable for administration to a patient. Both the first and second 'use' claim are referred to as Swiss-type claims. The theory behind the allowability of Swiss-type claims is that if the claimed use is for the 'manufacture' of an item, then the use is 'susceptible of industrial application' within the meaning of Article 52(1) EPC. Further, Articles 52(4) and 54 of the EPC specifically allow for the protection for product use with ultimate therapeutic methods of treatment, while at the same time adhering to the purpose of Article 52(4) EPC (i.e., protecting physicians from the burdens of patent infringement in non-commercial and non-industrial activities). See id at 397-398 and See Declaration of Alan Howarth, ¶'s 5-13.

The origin of the Swiss-type claim clearly establishes that the format particularly was established to claim methods of treatment. Reference to Swiss law defines Swiss-type claims as compounds subject of a prior right, which do not meet the prior art conditions with respect to their use in the implementation of a method of therapeutic treatment or diagnosis. Petrova, Albena, From the Amazon to the Alps..., 15 Pace Int'l L. Rev 247, 250 (2003))(A courtesy copy is enclosed with this response and listed on an IDS) citing Loi fédérale du 25 juin 1954 sur les brevets d'invention, Legge federale del 25 giugno 1954 sui brevetti d'invenzione, Bundesgesetz vom 25. Juni 1954 über die erfindungspatente [Switzerland Federal Law on Patents for Inventions], RO 1955 893, RU 1955 899, AS 1955 871, art. 7(c) (1954) (amended 1995)(*supra*). As can be seen, Swiss-type claims clearly covered methods of treatment prior to August 25, 1997, the filing date of the present application, and do to this day. Accordingly, Applicant does have written description of a method of treatment claim. See Declaration of Alan Howarth, ¶'s 5 and 14.

Further, rather than merely be addressed to the use in the "preparation of a pharmaceutical for the treatment of symptoms associated with rheumatoid arthritis," original claim 1 reads "[u]se of erythropoietin or a substance having erythropoietin-like activity in the preparation of a pharmaceutical for the **treatment of chronic inflammations**" (emphasis added). Similarly, original claim 6 recites "wherein the symptoms treated comprise at least one of the group of morning stiffness, painful and swollen joints, loss of grip strength and pain." Thus, the original claims clearly disclose that the pharmaceutical preparation is used for the treatment of chronic

inflammations and symptoms of RA. See Declaration of Alan Howarth, ¶'s 16-18.

Additionally, the originally filed specification clearly discloses that "EPO is used... for the treatment of chronic inflammations" and "[s]ignificant effects are seen in clinical variables such as morning stiffness, swollen joints, and the like" (see, originally filed abstract). Also, "significant decrease in the number of tender joints was already observed after two weeks of treatment." (page 3, lines 11-12, of the specification). Page 1, lines 13-25 of the specification provides a listing of a number of conditions that may be treated in accordance with the present invention. Page 6, lines 16-19 of the specification even provides one exemplary treatment protocol. The present claims are thus supported in the as-filed specification and the "new matter" rejection should be withdrawn. See Declaration of Alan Howarth, ¶'s 16-18.

The Office Action further contends that the term "painful joints" is "recited nowhere in the specification" and "this limitation finds support only in the method of preparing a pharmaceutical recited in the original 'use' claims." (Office Action at page 3). Applicant respectfully notes that originally filed claims are considered part of the specification. Thus, a method where a pharmaceutical preparation is used for the treatment of the symptom of "painful joints" is clearly supported by the specification in originally filed claim 6 (set forth previously herein). See Declaration of Alan Howarth, ¶'s 16-18.

Claims 18, 20, 23-26, and 31-36 further stand rejected under 35 USC §112, 1st ¶ for a lack of written description. The Examiner further contends that there is no written description for a method of treatment consisting of identifying a patient, administering Epo to said patient, and identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment. Further, the Examiner contends that there is no written description of a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient, administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level. Applicant respectfully requests reconsideration in light of this response. See Declaration of Alan Howarth, ¶'s 16-18.

A review of the specification discloses that the new limitations are found in the examples, at least, as admitted by the Examiner. The Examiner attempts to restrict the breadth of disclosure by remarking that the examples only disclose treating ACD patients with a specific dosage of Epo, for a specific timeframe. However, one of ordinary skill in the art would understand the disclosed methods of treatment would be applicable to the treatment of all rheumatoid arthritis patients. See Declaration of Alan Howarth, ¶'s 16-18.

In light of the overwhelming support that the originally submitted 'use' claims provide written description for a method treatment to one of ordinary skill in the art as claimed in claims 18, 20, 23-26, and 31-36, Applicant respectfully requests reconsideration of the rejection.

The Examiner contends that the "specification and claims as originally filed do not provide support for the invention as now claimed," specifically identifying a "method of treating consisting of identifying a patient, administering Epo to said patient, and identifying that said patient suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment" and "a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient, administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level." (Office Action at pages 3-4) Applicant respectfully traverses this rejection.

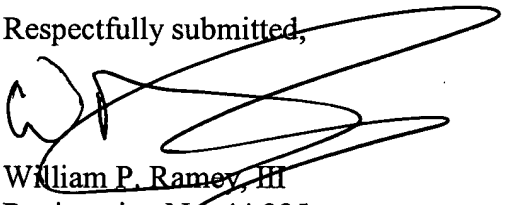
Evidence and actual examples are shown starting on page 6 of the as-filed specification, methods of "Treatment" are clearly described. The various acts of the method claims are supported by this section. In addition to providing exemplary dosage and administration protocols, the specification notes that "clinical and laboratory evaluation was performed at entry and weekly by the same physician, till the end of the study, then at 9 and 12 weeks after onset of the study." Erythrocyte sedimentation rate (ESR) was measured by the Westergren method. Assessments of the Ritchie index, grip strength, number of swollen joints, morning stiffness and a subjective pain score (visual analogue scale 0-10 points) were obtained. (see, the last paragraph on page 6 of the as-filed specification). Thus, one of ordinary skill in the art would readily understand that measurements were taken to identify patients suffering from the various

symptoms and that measurements were taken during and after the study to determine that the symptoms had been reduced by the treatment. The "identifying" actions of the present claims are thus also supported in the specification. Table III on page 11, Table IV on page 12 and Table V on page 13 each demonstrate the effectiveness of such methods. See Declaration of Alan Howarth, ¶'s 16-18. Accordingly, methods of treatment are specifically disclosed and Applicant respectfully requests reconsideration.

CONCLUSION

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein. Further, Applicant respectfully petitions for a three-month extension of time, the fee for which is included on a check submitted with this response.

Respectfully submitted,



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